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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,737	01/16/2001	Alan Wayne Henley	7175-67612	7500

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04/01/2003

Barnes & Thornburg
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EXAMINER

LEWIS, KIM M

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 04/01/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,737

Applicant(s)

HENLEY ET AL.

Examiner

Kim M. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-85 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32, 54, 65 and 74 is/are allowed.
- 6) ☒ Claim(s) 33-35, 45-53, 56-64, 66-73 and 75-85 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 1/13/03 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 1/13/03 has been received and made of record in the application file wrapper. The specification has been amended as requested. Claims 33, 45, 46, 54, 55, 58, 65-67, 74 and 76-78 have been amended, and new claim 86 has been added.

Drawings

2. The corrected or substitute drawings were received on 1/13/03. These drawings are approved by the examiner.

Terminal Disclaimer

3. The terminal disclaimer filed on 1/13/03 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US Patent No. 6,458,109 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischmann.

As regards claim 33, Fleischmann discloses a wound treatment apparatus comprising a bandage (12) having a fluid drainage passageway therein for insertion of a fluid drainage tube (16). Fleischmann further discloses a first drainage receptacles (28) coupled to the drainage tube (26), and a first valve (34) in the form of clamps coupled between the fluid drainage tube and the first drainage receptacle.

Fleischmann fails to teach a second drainage receptacle and a second drainage valve. However, it has been held that duplicating components of a prior art device is a design consideration within the level of ordinary skill in the art. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)

As such, one having ordinary skill in the art would have been motivated to duplicate the drainage receptacle and valve in order to provide an additional receptacle to receive the fluid drained from the pad and wound.

8. Claims 33-34, 45, 49-53, 55-57, 60-62, 64, 66, 69-73, 75-77, 80-83 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Westaby et al. in view of Fleischmann.

Regarding claims 33 and 34, Westaby et al. disclose all features of the claimed invention including a wound irrigation device comprising, a bandage including a wound backing surface configured to face toward the wound and a fluid drainage passageway having an opening adjacent the wound facing surface and a fluid drainage tube coupled to the fluid drainage passageway (col. 2, lines 40-50, col. 2, lines 53-65, and Fig. 1).

Westaby et al. fail to teach first and second fluid drainage receptacles coupled to the drainage tube and first and second valves coupled between the fluid drainage tube and first and second fluid drainage receptacles, respectively.

Fleischmann discloses a wound treatment device comprising a first and second fluid drainage receptacle coupled to a fluid drainage tube having therein a first valve for the purpose of containing the fluid removed from the wound site.

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As discussed above, it would have been obvious to one having ordinary skill in the art to modify Fleischmann with the addition of a second drainage receptacle and a second drainage valve in order to provide an additional receptacle to receive the fluid drained from the pad and wound.

In view of the modified device of Fleischmann, it would have been obvious to one having ordinary skill in the art to modify Westaby et al. by adding fluid drainage receptacles and corresponding valves for the purpose of containing the fluid removed from the wound site.

As regards claims 45, 50, 51, 55, 60, 61, 66, 70, 71, 76, 80, 81 and 85, Westaby et al. disclose a flexible, transparent cover/sheet having a plurality of apertures/passageways (20, 22) through which fluid may be added to or removed from a wound (page 2, lines 5-11 and lines 5-59).

Westaby et al. fail to teach a negative pressure source. However, Fleischmann discloses that the pad (12) is suctioned off, thereby teaching a negative vacuum source, in order to drain the pad and wound site.

In view of Fleischmann, one having ordinary skill in the art would have found it obvious to connect a negative pressure source to the outlet in order to remove fluid from the wound site. Such a configuration is conventionally known in the wound irrigating art.

Additionally, the examiner wishes the applicant to note that the device of Westaby et al., once modified to include the vacuum source, is **capable** of communicating negative pressure established by the vacuum source through the apertures/passageways.

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As regards claim 49, Westaby et al. fail to teach the plurality of apertures/passageways are arranged in a circle. Absent a critical teaching and/or a showing of unexpected results derived from placing the apertures/passageways in a circle, the examiner contends that such a configuration is an obvious design choice, which does not patentably distinguish applicant's invention.

As regards claim 52, Westaby et al. disclose the cover/sheet is constructed from a synthetic plastics material. Westaby et al. fail to teach the cover/sheet is impermeable. However, given the environment in which the device is used, the examiner contends that one having ordinary skill in the art would have been motivated to construct the cover/sheet from an impermeable plastic material in order to both prevent the fluid added to the wound site from escaping through the cover/sheet and to prevent the fluid from the wound from escaping and contaminating the surrounding environment.

As regards claim 53, note rim (14).

As regards claim 56, one aperture/passageway removes fluid from the wound that was added by the other aperture/passageway.

As regards claim 57, note the rejection of claim 49 above.

As regards claim 62, note the rejection of claim 52 above.

As regards claim 64, note the rejection of claim 53 above.

As regards claim 69, note the rejection of claim 49 above.

As regards claim 72, note the rejection of claim 52 above.

As regards claim 73, note the rejection of claim 53 above.

As regards claim 75, the apertures/passageways are **capable** of communicating fluid from the fluid source once modified.

As regards claim 77, note the rejection of claim 49 above.

As regards claim 82, note the rejection of claim 52 above.

As regards claim 83, note the rejection of claim 53 above.

As regards claim 85, see the rejection of claim 75 above.

9. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischmann in view of U.S. Patent No. 5,690,815 ("Krasnoff et al.").

As regards claim 35, Fleischmann fails to teach a sensor. However, Krasnoff et al. teach it is conventional to provide sensors on devices used to process fluids for the various reasons including indicating.

In view of Krasnoff et al., it would have been obvious to one having ordinary skill in the art to modify Fleischmann with addition of a sensor for the purpose of indicating various components as they relate to the fluid.

10. Claims 48 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Westaby et al. in view Fleischmann as applied to claims 45 and 55, respectively, and in further view Hunt et al.

As regards claims 48 and 63, Westaby et al. fail to teach a multi-lumen tube coupled to the bandage. However, Hunt et al. teach it is conventional in the art to

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couple a multi-lumen tube to a bandage for the purpose decreasing the amount of separate tubes supplied to the bandage.

In view of Hunt et al., it would have been obvious to one having ordinary skill in the art to modify the bandage of Westaby et al. by replacing the separate tubing with a multi-lumen tube for the purpose of decreasing the amount of separate tubes supplied to the bandage.

Claims 55, 58, 59, 76, 78 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tachibana et al in view of Fleischmann.

As regards claims 55, 58, 59, 76, 78 and 79, Tachibana et al. disclose a device capable of treating a wound comprising a first sheet/bandage (11) having a plurality of apertures/passageways through which the fluid delivery and fluid drainage conduits are inserted, a second sheet/bandage (14) having a perimeter and being both aligned and coupled with the perimeter of the first sheet/bandage, and a fluid source (18). The applicant should note that the second sheet does not have any apertures, thereby having a lesser number of apertures than the first sheet.

Tachibana et al. fail to teach a negative pressure source. However, Fleischmann discloses that the pad (12) is suctioned off, thereby teaching a negative vacuum source, in order to drain the pad and wound site.

In view of Fleischmann, one having ordinary skill in the art would have found it obvious to connect a negative pressure source to the outlet in order to remove fluid from the wound site.

Allowable Subject Matter

11. Claims 32, 54, 65 and 74 are allowed.

Response to Arguments

In response to applicants' argument that Fleischmann does not disclose or suggest "a bandage including a wound facing surface configured to face toward a wound and a fluid drainage passageway having an opening adjacent the wound facing surface", the examiner disagrees. It can be clearly seen from Fig. 1, that pad (12) is configured to face the wound surface and that a passageway, extending into the wound has an opening ***adjacent*** the wound facing surface. The applicant should note that the term ***adjacent*** has been given its broadest interpretation.

The additional arguments presented by the applicant's are moot in view of the new grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Mondays and Tuesdays from 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703.308.1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703.305.3590 for regular communications and 703.305.3590 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.



Kim M. Lewis
Primary Examiner
Art Unit 3761

kml
March 24, 2003